

## § 225.30

from litter, waste, refuse, uncut weeds or grass, standing water, and improperly stored equipment.

(2) The building(s) shall be maintained in a reasonably clean and orderly manner.

(3) The building(s) shall be of suitable construction to minimize access by rodents, birds, insects, and other pests.

(4) The buildings shall provide adequate space and lighting for the proper performance of the following medicated feed manufacturing operations:

(i) The receipt, control, and storage of components.

(ii) Component processing.

(iii) Medicated feed manufacturing.

(iv) Packaging and labeling.

(v) Storage of containers, packaging materials, labeling and finished products.

(vi) Routine maintenance of equipment.

## § 225.30 Equipment.

(a) Equipment which is designed to perform its intended function and is properly installed and used is essential to the manufacture of medicated feeds. Such equipment permits production of feeds of uniform quality, facilitates cleaning, and minimizes spillage of drug components and finished product.

(b)(1) All equipment shall possess the capability to produce a medicated feed of intended potency, safety, and purity.

(2) All equipment shall be maintained in a reasonably clean and orderly manner.

(3) All equipment, including scales and liquid metering devices, shall be of suitable size, design, construction, precision, and accuracy for its intended purpose.

(4) All scales and metering devices shall be tested for accuracy upon installation and at least once a year thereafter, or more frequently as may be necessary to insure their accuracy.

(5) All equipment shall be so constructed and maintained as to prevent lubricants and coolants from becoming unsafe additives in feed components or medicated feed.

(6) All equipment shall be designed, constructed, installed and maintained so as to facilitate inspection and use of cleanout procedure(s).

## 21 CFR Ch. I (4–1–07 Edition)

## § 225.35 Use of work areas, equipment, and storage areas for other manufacturing and storage purpose.

(a) Many manufacturers of medicated feeds are also involved in the manufacture, storage, or handling of products which are not intended for animal feed use, such as fertilizers, herbicides, insecticides, fungicides, rodenticides, and other pesticides. Manufacturing, storage, or handling of nonfeed and feed products in the same facilities may cause adulteration of feed products with toxic or otherwise unapproved feed additives.

(b) Work areas and equipment used for the manufacture or storage of medicated feeds or components thereof shall not be used for, and shall be physically separated from, work areas and equipment used for the manufacture of fertilizers, herbicides, insecticides, fungicides, rodenticides, and other pesticides unless such articles are approved drugs or approved food additives intended for use in the manufacture of medicated feed.

## Subpart C—Product Quality Control

## § 225.42 Components.

(a) A medicated feed, in addition to providing nutrients, is a vehicle for the administration of a drug, or drugs, to animals. To ensure proper safety and effectiveness, such medicated feeds must contain the labeled amounts of drugs. It is necessary that adequate procedures be established for the receipt, storage, and inventory control for all such drugs to aid in assuring their identity, strength, quality, and purity when incorporated into products.

(b) The receipt, storage, and inventory of drugs, including undiluted drug components, medicated premixes, and semiprocessed (i.e., intermediate premixes, inplant premixes and concentrates) intermediate mixes containing drugs, which are used in the manufacture and processing of medicated feeds shall conform to the following:

(1) Incoming shipments of drugs shall be visually examined for identity and damage. Drugs which have been subjected to conditions which may have